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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/352,466	07/13/99	BROUDY	A-195CDD

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AMGEN INCORPORATED  
MAIL STOP 27-4-A  
ONE AMGEN CENTER DRIVE  
THOUSAND OAKS CA 91320-1799

EXAMINER	
HELMS, L	
ART UNIT	PAPER NUMBER
1642	9

DATE MAILED: 03/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No.  
**09/352,466**

Applicant(s)

**Broudy et al**

Examiner  
**Larry R. Helms Ph.D.**

Group Art Unit  
**1642**



☒ Responsive to communication(s) filed on 16 Jan 2001

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-25 is/are pending in the application.

Of the above, claim(s) 1-20 and 22-25 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 21 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4 and 8

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

1. Applicant's election of Group IX, claim 21 in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-20 and 22-25 are withdrawn from further consideration as being drawn to non-elected inventions.
3. Claim 21 is under examination.

### ***Specification***

4. The disclosure is objected to because of the following informalities:
  - a. The first line of the specification should be updated to include all applications to which the instant application is claiming benefit from. The priority applications should indicate there current status.
  - b. The specification needs to be updated to indicate the current status of all co-pending applications, for example, page 1, lines 15-17.
  - c. The specification needs to be updated to indicate the ATCC accession number, for example on page 13, line 15 and page 31, line 7 and date of deposit.
  - d. The specification should be updated to indicate the new ATCC address which is  
10801 University Boulevard, Manassas, VA 20110-2209.

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e. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Appropriate correction is required.

### ***Claim Objections***

5. Claim 21 is objected to because of the following informalities: Claim 21 is dependent on non-elected claim 1. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 21 is indefinite for reciting an incomplete method claim does not include a resolution step which reads back on the preamble of the claimed method. Merely administering a

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SCF inhibiting amount of an antibody does not result in a method of modifying sensitivity to a cell cycle-specific chemotherapeutic agents. The claims should conclude with a step of thereby modifying the sensitivity to cell cycle-specific chemotherapeutic agents, for example, thereby producing a method as recited in the preamble.

b. Claim 21 is indefinite because the claim contains the abbreviation “SCF”. Full terminology should be in first instance of the claims followed by the abbreviation in parentheses.

Dependent claims may then use the abbreviation. Abbreviations render the claim indefinite because the same abbreviation may represent more than one element or concept.

c. Claim 21 is indefinite for reciting “modifying sensitivity to cell cycle-specific chemotherapeutic agents” because the exact meaning of the phrase is not clear. It is not clear what “modifying” is meant to encompass or what is being modified . In addition, does the method increase the sensitivity or decrease the sensitivity?. Moreover, it is unclear what compounds are encompassed by “cell cycle-specific chemotherapeutic agents” because the specification lacks a clear definition of this phrase.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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9. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The specification teaches an antibody which inhibits the binding of an SCF molecule to an SCF receptor, specifically one antibody designated SR-1 (see page 7, lines 1-2 and page 13, lines 11-15). The specification only mentions a method for modifying sensitivity to cell cycle-specific chemotherapeutic agent comprising administering an SCF-inhibiting amount of a monoclonal antibody (see pages 20-21). The specification fails to teach how to perform the method and complete method steps. Thus, undue experimentation would be required to perform the claimed method.

Further, the disclosure does not provide working examples wherein all of the steps required to practice the method are employed. Lack of working examples is given added weight in cases involving an unpredictable and undeveloped art such as cancer. In the instant case, the claims are so broadly drawn, the guidance is so limited, and the art is so unpredictable that

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skilled artisan is presented with a multitude of un-linked alternatives with no guidance as to which will enable use of the invention as claimed. Among these are (i) what sensitivity is modified, (ii) what specific cell cycle-specific chemotherapeutic agents to select, (iii) what cells to target or select, (iv) which of many diseases to select, and (v) what dosage, schedule, and route of administration will provide a successful outcome.

Therefore, due the unpredictability of cancer therapy and in view of the insufficient guidance and/or working examples concerning the use the claimed antibodies in a method of modifying sensitivity, one skilled in the art would not know how to practice the broadly claimed invention, i.e., administer antibodies for modifying sensitivity to cell cycle-specific chemotherapeutic agents without undue experimentation.

### *Conclusions*

10. No Claims are allowed. Due to the indefinite nature of the claim and the lack of enablement provided in the specification, a proper search of the claim could not be performed. Applicant is advised that upon amendment to the claim to clarify the indefinite nature of the claim may result in prior art applied to the claim(s) and may result in the action being made final.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The

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examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

  
SHEELA HUFF  
PRIMARY EXAMINER